

Food and Drug Administration, HHS

§ 1.276

registration system and the system generates a confirmation.

[68 FR 58960, Oct. 10, 2003 as amended at 73 FR 15883, Mar. 26, 2008]

ADDITIONAL PROVISIONS

§ 1.240 What other registration requirements apply?

In addition to the requirements of this subpart, you must comply with the registration regulations found in part 108 of this chapter, related to emergency permit control, and any other Federal, State, or local registration requirements that apply to your facility.

§ 1.241 What are the consequences of failing to register, update, or cancel your registration?

(a) Section 301 of the act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, to update required elements of its facility's registration, or to cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the act.

(b) FDA will cancel a registration if the agency independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist. If FDA cancels a facility's registration, FDA will mail a confirmation of the cancellation to the facility at the address provided in the facility's registration.

(c) If an article of food is imported or offered for import into the United States and a foreign facility that manufactured/processed, packed, or held that article of food has not registered in accordance with this subpart, the disposition of the article of food shall be governed by the procedures set out in subpart I of this part.

§ 1.242 What does assignment of a registration number mean?

Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

§ 1.243 Is food registration information available to the public?

(a) The list of registered facilities and registration documents submitted under this subpart are not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act). In addition, any information derived from such list or registration documents that would disclose the identity or location of a specific registered person, is not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act).

(b) Paragraph (a) of this section does not apply to any information obtained by other means or that has previously been disclosed to the public as defined in § 20.81 of this chapter.

Subpart I—Prior Notice of Imported Food

SOURCE: 73 FR 66402, Nov. 7, 2008, unless otherwise noted.

GENERAL PROVISIONS

§ 1.276 What definitions apply to this subpart?

(a) *The act* means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart, unless defined in this section.

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article originates* means FDA Country of Production.